K030475

a. Summary Of Safety And Effectiveness

MAR 1 4 2003

Contact Person

Jim Leathley
Regulatory Affairs Project Manager
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA. 94538

Trade Name

Guglielmi Detachable Coil (GDC®)

Common Name

Occlusion Coil

Classification Name

Artificial Embolization Device (21 CFR Section 882.5950)

Predicate Devices

Number	Description	Predicate for	Clearance Date
K001083 (Boston Scientific Target)	Guglielmi Detachable Coil (GDC) - Additional Version 4 Modifications	GDC 10-Soft SR GDC 10-Soft 2D SR	3 May 2000
K002181 (Boston Scientific Target)	GDC 10-UltraSoft Coil	GDC 10-UltraSoft	11 August 2000

Device Description

Guglielmi Detachable Coils (GDC®) are used as part of a system indicated for endovascular occlusion in patients with high surgical risk intracranial aneurysms and other neurovascular abnormalities.

The GDC system consists of the following items, each of which is sold separately

- GDC Power Supply
- GDC SynerG ™ occlusion coil attached to a delivery wire
- set of GDC connecting cables
- patient return electrode
- two 9-volt batteries

GDC SynerG coils are available in regular (secondary helical), 2D (secondary helical with distal helix) and 3D (tertiary) shapes, in a range of sizes, and in Standard, Soft and Stretch Resistant versions, all of which are compatible with Boston Scientific Target Infusion Catheters with two tip markers. GDC is also available as an UltraSoft™ Coil, developed to address physicians' requests for a softer Stretch Resistant coil and a wider range of coil sizes to treat intracranial aneurysms. Boston Scientific Target also offers a Fibered GDC device, *GDC 18-Fibered VortX Shape*, incorporating synthetic fibers through the main coil for a more rigid coil.

All of the coils are manufactured from a platinum-tungsten alloy wire which is wound into a primary or main coil. Depending upon the desired final configuration, a coil is either formed into a secondary helical shape (standard and Stretch Resistant GDC), vortex shape (GDC-18 Fibered VortX) or tertiary shape (3D GDC). The distal tip of the coil is welded to form a smooth tip (with the exception of Stretch Resistant GDC). The coils are attached to a delivery wire, which consists of a ground stainless-steel core wire with a stainless-steel coil welded at the distal end and a Teflon® outer jacket.

Using fluoroscopic guidance and a guiding catheter to access the lesion, the physician delivers the GDC coil to the targeted site through an infusion catheter.

Upon desired placement in the anatomy, the coil is detached by use of a battery-operated power supply designed specifically for use with the GDC system. The GDC SynerG Power Supply used to initiate and control detachment is a self-contained unit that applies a constant current through the GDC system until detachment is detected.

Each time the GDC Power Supply is turned on, the unit defaults to the 1.0 mA current setting. Pressing the "Current" switch one time changes the setting to the 0.5 mA current setting; pressing a second time changes the setting to 0.75 mA; pressing a third time returns the unit to the default 1.0 mA setting. Each time the switch is pressed, the current display flashes the new current setting.

After selecting a current setting and initiating detachment, the current flowing through the delivery wire begins to dissolve, by electrolysis, the exposed stainless steel at the junction with the platinum-tungsten coil. Over a period of several minutes, the exposed steel completely dissolves and the platinum-tungsten coil detaches. When coil detachment is detected, the GDC SynerG Power Supply immediately halts current flow, freezes the displays and emits an audible signal that coil detachment has occurred. Using fluoroscopy, the physician then verifies that the

delivery wire can be withdrawn without disturbing the newly placed coil, and can resume electrolysis if necessary.

Multiple GDC coils may be placed within a single aneurysm, at the discretion of the interventional team, to achieve optimum occlusion of the lesion.

Intended Use

GDC Coils (All Versions except GDC 18-Fibered VortX™ Shape):
The Guglielmi Detachable Coil is intended for embolization of those intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) inoperable. The GDC is also intended for embolization of other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

GDC 18-Fibered VortX Shape:
This product is intended for embolization of vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature. GDC-18 Fibered VortX Shape is also intended for arterial and venous embolizations in the peripheral vasculature.

Technological Characteristics Comparison

Coil Dimensional Attributes (compared to the predicate device)

	GDC 10-Soft SR with anchor chain GDC 10-Soft 2D SR with anchor chain GDC 10-UltraSoft™ Coil with anchor chain
Coil Primary Wind OD	Same as predicate device.
Secondary Coil OD	Same as predicate device.
Coil Wire OD	Same as predicate device.
Delivery Wire Length	Same as predicate device.
Delivery Wire Proximal OD	Same as predicate device.
Delivery Wire Distal OD	Same as predicate device.

Technological Characteristics Comparison (cont.)

Materials

	GDC 10-Soft SR with anchor chain GDC 10-Soft 2D SR with anchor chain GDC 10-UltraSoft™ Coil with anchor chain
Main Coil	Same as predicate device
Stretch Resistant Thread	Same as predicate device
Main Coil / delivery wire junction tubing	Same as predicate device
Anchor (for Stretch Resistant Thread)	Two-piece anchor chain (replaces one-piece anchor twister)
Delivery Wire	
Core wire w/coating	Same as predicate device
Proximal Coil	Same as predicate device
Proximal Marker Coil	Same as predicate device
Sheath, Delivery Wire (heat shrink tubing)	Same as predicate device
Proximal Tubing	Same as predicate device
Bushing	Same as predicate device
Inner Coil	Same as predicate device

Verification Test Summary Table:
Predicate GDC Devices vs Modified Devices

Test or Point of Comparison	**GDC 10-Soft SR with anchor chain** **GDC 10-Soft 2D SR with anchor chain** **GDC 10-UltraSoft™ Coil with anchor chain**
Tensile Strength	Meets acceptance criteria.
Friction	Meets acceptance criteria.
Detachment Time	Modification has no affect upon detachment time.
Deployment / Retraction Force	Meets acceptance criteria.
Tip Ball Strength	Meets acceptance criteria.
Coil Migration	Modification has no affect upon coil migration.
Coil Stiffness	Meets acceptance criteria.
Inner Coil Weld Strength	Modfication has no affect upon inner coil weld strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2003

Mr. Jim Leathley
Regulatory Affairs Project Manger
Boston Scientific Target
47900 Bayside Parkway
Fremont, California 94538

Re: K030475
Trade/Device Name: Guglielmi Detachable Coil (GDC®)
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: February 12, 2003
Received: February 13, 2003

Dear Mr. Leathley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030475

Boston Scientific TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: GDC 10-Soft SR
GDC 10-Soft 2D SR
GDC 10-UltraSoft

Indications for Use:

GDC / Stretch Resistant GDC

The Guglielmi Detachable Coil (GDC) is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over The Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030475